K092888

NOV 10 2009

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter Name, Address, Contact Information

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Date Prepared: September 8, 2009

Device Name

Proprietary name: Elecsys Toxo IgG CalCheck 5
Common name: Toxo IgG CalCheck 5
Classification name: Single (specified) analyte controls (assayed and unassayed)

Predicate Device

The Elecsys Toxo IgG CalCheck 5 is substantially equivalent to the Elecsys Toxo IgG CalCheck (K083655).

Device Description

The Elecsys Toxo IgG CalCheck 5 is a lyophilized product consisting of a defined concentration of human anti-Toxoplasma gondii IgG antibodies in a human serum matrix. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.

Intended Use

The Elecsys Toxo IgG CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Toxo IgG reagent on the Elecsys 2010, MODULAR ANALYTICS E170 and **cobas e** immunoassay analyzers.

Comparison Table

The table below compares Elecsys Toxo IgG CalCheck 5 with the predicate device, Elecsys Toxo IgG Calcheck (K083655).

Characteristic	Elecsys Toxo IgG CalCheck (K083655)	Elecsys Toxo IgG CalCheck 5
Intended Use	The Elecsys Toxo IgG CalCheck, an assayed calibrator control, is intended for use in the verification of the calibration established by the Elecsys Toxo IgG reagent on the Elecsys 2010, the MODULAR ANALYTICS E170 and **cobas e** immunoassay analyzers.	The Elecsys Toxo IgG CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Toxo IgG reagent on the Elecsys 2010, MODULAR ANALYTICS E170 and **cobas e** immunoassay analyzers.
Levels	Three	Five
Reactive Component	Anti-Toxo IgG antibody	Same
Format	Lyophilized	Same
Handling	Reconstitute the contents of each vial with exactly 1.0 mL distilled or deionized water. Allow the bottle to stand closed for 15 minutes. Mix gently by inversion to ensure homogeneity.	Same
Stability	Unopened: • Store at 2-8°C until expiration date Reconstituted: • 20 – 25°C : 4 hrs	Same
Matrix	Human serum matrix	Same
Preservatives	None	Same
Traceability	The assay value of each level was calibrated against the WHO anti-Toxoplasma serum (TOXM), 3rd International Standard for *T. gondii* from NIBSC, UK.	Same

Performance Characteristics

The Elecsys Toxo IgG CalCheck 5 was evaluated for value assignment and stability.

Toxo IgG CalCheck 5 *(Draft)*

cobas®

IgG antibodies to *Toxoplasma gondii*

REF **05979650** 160 for 5 x 1.0 mL

• Indicates analyzers on which the kit can be used

Elecsys 2010	MODULAR ANALYTICS E170	**cobas e** 411	**cobas e** 601
•	•	•	•

English

Intended use

The Elecsys Toxo IgG CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Toxo IgG reagent on the Elecsys 2010, MODULAR ANALYTICS E170 and **cobas e** immunoassay analyzers.

Summary

Elecsys Toxo IgG CalCheck 5 set contains 5 lyophilized levels of human anti-Toxo IgG antibodies in a solution of human serum protein and has the appropriate matrix characteristics for the analyte. The solutions assist in the documentation of calibration verification and verification of the assay range.

Principle

Calibration verification is not a requirement of the Elecsys and **cobas e** immunoassay systems based on the manufacturer's recommendations. However, in instances where such a test procedure is required by certification agencies, or where the user wishes to document calibration verification, these CalCheck 5 solutions provide an appropriate material for such testing. College of American Pathologists, CAP, defines Calibration Verification by referring to two distinct processes: 1) validation of the current method calibration and 2) validation of the reportable range.[1]
CAP defines the ANALYTICAL MEASUREMENT RANGE (AMR) as the range of analyte values that a method can directly measure on the specimen without any dilution, concentration, or other pretreatment not part of the usual assay process.[1]

Reagents - working solutions

Check 1 - 5

Each set contains 5 lyophilized levels
Each bottle, reconstituted to 1.0 mL
Reactive ingredient (after reconstitution):
Toxo IgG antibody positive human serum in human serum matrix

Precautions and warnings

For in vitro diagnostic use.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.
Safety data sheet available for professional user on request.
All human material should be considered potentially infectious. All products derived from human blood are prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV. The testing methods applied were FDA-approved or cleared in compliance with the European Directive 98/79/EC, Annex II, List A. However, as no testing method can rule out the potential risk of infection with absolute certainty, the material should be treated just as carefully as a patient specimen. In the event of exposure the directives of the responsible health authorities should be followed.[2,3]
Avoid the formation of foam with all reagents and sample types (specimens, calibrators, and controls).

Reagent handling

Reconstitute the contents of Check 1, Check 2, Check 3, Check 4 and Check 5 with exactly 1.0 mL distilled or deionized water. Allow the bottles to stand closed for 15 minutes. Mix gently by inversion to ensure homogeneity. Refer to the lot-specific value sheet located on www.MyLabOnline.com for any lot-specific reconstitution changes.

Storage and stability

Store unopened at 2-8 °C.
Stability unopened: up to the expiration date printed on the bottle labels at 2-8 °C.
Stability reconstituted: 4 hours at 20-25 °C.

Materials provided

- Elecsys Toxo IgG CalCheck 5 Check 1, 2, 3, 4 and 5

Materials required (but not provided)

- Elecsys 2010, MODULAR ANALYTICS E170 or **cobas e** analyzer
- Elecsys Toxo IgG reagent kit
- Distilled or deionized water
- General laboratory equipment

Assay

• For calibration verification only, recommended levels are Check 2, 3 and 4.

1. Run each Elecsys Toxo IgG CalCheck 5 level in duplicate on the Elecsys or **cobas e** analyzer. Program the 6 samples as you would patient samples.
2. Determine the average value for each level and compare it to the appropriate acceptable range listed in the electronically available value sheet. The average value should fall within the specified limits.

If...	Then...
Check 2, Check 3 or Check 4 does not fall within the specified limits,	repeat to exclude error in technique. If recovery is still outside the specified limits, contact Customer Technical Support.

• For verification of the assay range only or verification of assay range and calibration verification, recommended levels are Check 1, 2, 3, 4 and 5.

1. Run each Elecsys Toxo IgG CalCheck 5 level in duplicate on the Elecsys or **cobas e** analyzer. Program the 10 samples as you would patient samples.
2. Determine the average value for each level and compare it to the appropriate acceptable range listed in the electronically available value sheet. The average value should fall within the specified limits.

If...	Then...
Check 1 extends below the measuring range,	mix equal parts of Check 1 and Check 2. Analyze the diluted sample in duplicate. This results in values above the low end of the assay range but below the value for Check 2. If recovery is still outside the specified limits, contact Customer Technical Support.
Check 5 exceeds the measuring range,	mix equal parts of Check 4 and Check 5. Analyze the diluted sample in duplicate. If recovery is still outside the specified limits, see next step.
the diluted sample of Check 4 and Check 5 from the previous step still exceeds the measuring range,	mix equal parts of Check 3 and Check 5. Analyze the diluted sample in duplicate. If recovery is still outside the specified limits, contact Customer Technical Support.
Check 2, Check 3 or Check 4 does not fall within the specified limits,	repeat to exclude error in technique. If recovery is still outside the specified limits, contact Customer Technical Support.

Note

To ensure sufficient volume to run the samples, it is recommended to use 250 µL.

Toxo IgG CalCheck 5 *(Draft)*

cobas®

IgG antibodies to *Toxoplasma gondii*

Results

Each laboratory should establish appropriate acceptance criteria when using this product for its intended use. Actual results obtained may vary depending on instrumentation. Results may also be dependent on the accuracy of the instrument/reagent/system calibration.

The following table lists approximate target ranges.

Refer to the value sheet located on www.MyLabOnline.com for lot-specific ranges.

Level	Approximate Target Range	Unit
Check 1	≤ 1.00	IU/mL
Check 2	2.10 - 3.90	IU/mL
Check 3	228 - 423	IU/mL
Check 4	364 - > 650	IU/mL
Check 5	455 - > 650	IU/mL

Traceability

The assay value of each level was calibrated against the WHO anti-Toxoplasma serum (TOXM), 3rd International Standard for T. gondii from NIBSC, UK.

Limitations

Elecsys Toxo IgG CalCheck 5 solutions are intended for use in the confirmation of assay calibration and verification of the assay range. This product is not intended to replace calibration or quality control materials. Refer to the appropriate operator's manual and/or package insert for analyzer-specific limitations.

Symbol legend

	Use by
LOT	Batch code
CONTENT	Contents of kit
	Manufacturer
IVD	In Vitro Diagnostic Medical Device
	Temperature limitation (Store at)
	Biological risks (Potentially biohazardous material)
REF	Catalogue number

References

1. College of American Pathologists User's Guide: Calibration Verification/Linearity Surveys. Chapter 3.
2. Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.
3. Council Directive (2000/54/EC). Official Journal of the European Communities No. L262 from Oct. 17, 2000.

FOR US CUSTOMERS ONLY: LIMITED WARRANTY

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

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NOV 10 2009

Re: K092888
Trade/Device Name: Elecsys Toxo IgG CalCheck 5
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJX, LGD
Dated: September 18, 2009
Received: September 21, 2009

Dear Ms. Phillips:

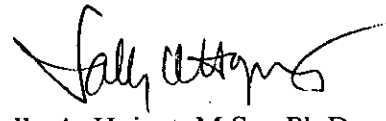
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Device Name: **Elecsys Toxo IgG CalCheck 5**

Indications For Use: The Elecsys Toxo IgG CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Toxo IgG reagent on the Elecsys 2010, MODULAR ANALYTICS E170 and **cobas e** immunoassay analyzers.

Prescription Use **XXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K092888